

**10 July 2014**  
**[13–14]**

## **Call for submissions – Proposal 1029**

### **Maximum Level for Tutin in Honey**

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FSANZ has assessed a proposal prepared to review the maximum levels for tutin in honey and comb honey and has prepared a draft food regulatory measure. Pursuant to section 61 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at [information for submitters](#).

All submissions on applications and proposals will be published on our website. We will not publish material that is provided in-confidence, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at [information for submitters](#).

Submissions should be made in writing; be marked clearly with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website via the link on [documents for public comment](#). You can also email your submission directly to [submissions@foodstandards.gov.au](mailto:submissions@foodstandards.gov.au).

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

### **DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 21 August 2014**

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making submissions or the application process can be sent to [standards.management@foodstandards.gov.au](mailto:standards.management@foodstandards.gov.au).

Hard copy submissions may be sent to one of the following addresses:

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## Supporting documents

The following documents which informed the assessment of this Proposal are available on the FSANZ website at <http://www.foodstandards.gov.au/code/proposals/Pages/P1029-Maximum-Level-for-Tutin-in-Honey.aspx>

- SD1 Risk Assessment
- SD2 Consultation Regulation Impact Statement

## Executive summary

Tutin is a plant-derived neurotoxin, which can sometimes be present in honey produced in New Zealand. Following a severe poisoning incident in New Zealand in 2008 temporary maximum levels (MLs) for tutin in honey and comb honey were adopted into the *Australia New Zealand Food Standards Code* (the Code) while further research and evaluation was conducted. The temporary ML of 2 mg/kg for tutin in honey was derived from animal studies using purified tutin. The temporary MLs are due to expire on 31 March 2015.

The main findings from the recent research show that:

- (i) in addition to tutin, dietary exposure also occurs due to the presence of tutin glycosides in honey that are broken down in the human gut to release more tutin some hours after consumption;
- (ii) in a human study, a tutin dose derived from the current temporary ML for honey was associated with mild adverse effects and therefore is not adequately protective of human health.

Based on the evidence, FSANZ has considered regulatory and non-regulatory options to appropriately manage the food safety risks posed by tutin contamination of honey. A consultation Regulation Impact Statement (RIS) has been completed for this Proposal which evaluates the costs and benefits of these options.

Based on this analysis, FSANZ is proposing a draft variation to reduce and make permanent the MLs for tutin in honey and comb honey in the Table to clause 5 of Standard 1.4.1. FSANZ proposes to reduce the ML for honey from 2 mg/kg to 0.7 mg/kg, and to change the ML for comb honey from 0.1 mg/kg to the current analytical limit of detection of 0.01 mg/kg. The proposed ML for comb honey is more conservative because defining MLs for comb honey that protect human safety is not possible as there are insufficient data on the degree of variability of tutin levels across combs. The continued use of MLs based on the level of tutin instead of total tutin equivalents (tutin + tutin glycosides) is necessary because there is no method currently available to quantify the tutin glycosides in honey.

Comments are sought from the honey industry on the questions raised in the RIS (in **Supporting Document 2**). These questions relate to the analysis of the options, current blending and testing costs, effects of reducing the MLs and the proposed implementation approach.

# 1 Introduction

## 1.1 Background

Tutin is a neurotoxic compound produced by the shrub *Coriaria arborea* ('tutu') which is native to New Zealand. Tutin contamination of New Zealand honey can occur when bees gather honeydew excreted from a vine hopper insect (*Scolypopa australis*) that feeds on the sap of tutu. The tutin present in the tutu sap is transferred to the vine hopper honeydew which is then transferred to honey.

Human poisonings associated with the consumption of tutin-containing honey have occurred sporadically in New Zealand since the late 19<sup>th</sup> Century. This issue appears to be unique to New Zealand. FSANZ is not aware of reports of poisoning from honey containing tutin in Australia or any other country. In New Zealand in 2008, at least 20 people were poisoned due to the consumption of honey containing tutin.

In December 2008, a New Zealand food standard for tutin in honey, issued under the New Zealand *Food Act 1981*, was introduced and came into force in January 2009 (NZFSA, 2008). The standard set a maximum level (ML) of 2 mg/kg for tutin in honey (extracted/blended honey)<sup>1</sup> and a ML of 0.1 mg/kg for comb honey based on a preliminary risk assessment carried out by the then New Zealand Food Safety Authority (now Ministry for Primary Industries, MPI). These MLs were introduced as an interim risk management measure in response to the poisoning episode.

FSANZ adopted these MLs in August 2009 as a temporary measure into Standard 1.4.1 – Contaminants and Natural Toxicants in the *Australia New Zealand Food Standards Code* (the Code). This was undertaken as part of Proposal P1008 – Code Maintenance Proposal VIII. These temporary MLs were considered to be an appropriate risk management measure while further research and evaluation was completed. The New Zealand food standard for tutin (NZFSA, 2008) provided options for demonstrating compliance with these MLs in the Code. This has since been replaced with the 2010 New Zealand standard (MAF, 2010).

The temporary MLs in the Code were initially due to expire on 31 March 2011. FSANZ extended the expiry date, ultimately to 31 March 2015, to allow time for further research and evaluation. The extensions to the expiry date were made under Proposals P1009 – Maximum Limits for Tutin in Honey and P1023 – Tutin, Tocopherol & Food for Special Medical Purposes Amendments.

## 1.2 The Proposal

The purpose of this Proposal is to review the adequacy and appropriateness of the current risk management measure for tutin in honey and comb honey (i.e. the MLs for tutin in Standard 1.4.1.)

## 1.3 The current Standards

### 1.3.1 *Australia New Zealand Food Standards Code*

Standard 1.4.1 currently prescribes temporary MLs for tutin in honey at 2 mg/kg and comb honey at 0.1 mg/kg. These are listed in the table to clause 5 of the Standard. These levels will expire on 31 March 2015 (subclause 5(5) of the Standard).

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<sup>1</sup> When referring to 'honey' and not 'comb honey', the terms 'extracted' or 'blended' are commonly used to assist in further distinguishing 'honey' from 'comb honey'.

The Standard also provides a formula to determine the ML which applies to a contaminant or natural toxicant in a mixed food (subclause 1(6) of the Standard).

Standard 1.4.4 – Prohibited and Restricted Plants and Fungi currently prohibits the tutu plant (species *Coriaria* spp. as listed in Schedule 1), or a part or derivative of the plant, or a substance derived from the plant, from being intentionally added to food or offered for sale as food.

### 1.3.2 New Zealand Standard

In New Zealand, the Food (Tutin in Honey) Standard 2010 (MAF, 2010) issued under the *Food Act 1981*, provides a number of options for demonstrating compliance with the tutin MLs in the Code. MPI is responsible for developing and administering this standard (the New Zealand tutin standard).

The New Zealand tutin standard requires the last person to pack honey for sale for human consumption and any person who is exporting honey to demonstrate compliance with the ML. The options provided in the standard for demonstrating compliance for instance, record keeping options demonstrating a low risk harvest date<sup>2</sup> or low risk location<sup>3</sup>, and options relating to sampling and testing.

MPI is currently reviewing this standard. The existing 2010 standard and the compliance options it provides will continue to remain in place pending the outcome of this review. This review is a separate and independent process to the FSANZ Proposal P1029 outlined in this report on the tutin MLs in the Code.

## 1.4 Reasons for preparing the Proposal

This Proposal was prepared to review the MLs for tutin in honey and comb honey in Standard 1.4.1, taking account of recent research, before the existing temporary MLs expire.

## 1.5 Procedure for assessment

The Proposal is being assessed under the General Procedure.

# 2 Summary of the assessment

## 2.1 Risk assessment

FSANZ's risk assessment for tutin in honey is provided in **Supporting Document 1 (SD1)**.

Consumption of honey containing tutin has resulted in serious acute adverse health effects. In response a temporary ML of 2 mg/kg for tutin was established using data derived from the oral administration of purified tutin in mice. It was noted that in some human poisoning cases the onset of adverse effects was much slower than observed in mice. To investigate this difference, a human kinetic study was conducted. Following ingestion of honey naturally contaminated with tutin it was revealed by analysis of tutin levels in blood that there were two peaks rather than the expected one. Subsequent experiments led to the discovery of tutin glycosides, a 'masked' form of tutin, in honey in addition to free tutin. The time taken to convert this 'masked' form of tutin to free tutin explained the larger second peak observed in blood.

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<sup>2</sup> **Low risk harvest date** applies to honey that has been taken from honey supers placed onto hives after 1 July and before 31 December of any year.

<sup>3</sup> **Low risk area** is the South Island below latitude 42 degrees South including all offshore islands below latitude 42 degrees South.

The timing of the second peak also corresponded to the onset of headaches in some of the volunteers. These findings indicated that there was more tutin in extracted honey samples than had been measured. Hence the current temporary ML for tutin in honey, which was based on the toxicity of pure tutin in an animal study, was not considered to be adequately protective of human health and safety because it does not take account of the presence of tutin glycosides in honey.

No method is currently available to reliably quantify 'masked' tutin in honey. Therefore the continued use of an ML based on the level of free tutin is necessary. FSANZ has calculated that a reduction of the current temporary ML from 2 mg/kg to 0.7 mg/kg for extracted/blended honey should provide an adequate margin of safety for consumers.

There are insufficient data available on the degree of variability in levels of both forms of tutin across honey combs.

## **2.2 Risk management**

FSANZ has considered both regulatory and non-regulatory options. The non-regulatory options considered include the *status quo* where the existing MLs in the Code would expire with no new levels or measures in place, and the development of an industry code of practice. The regulatory options considered include maintaining the existing MLs in the Code as a permanent measure, or setting new reduced MLs based on recent scientific research. Each of these options have been analysed in the consultation Regulation Impact Statement (RIS) for this Proposal (see section 2.4.1.1 below and SD2).

Currently, the risk of tutin poisoning is managed in the Code by prescribing MLs for tutin. Other more restrictive regulatory measures, such as prohibiting the production of honey in certain areas, were considered to be unnecessary options and were not analysed as part of the RIS. FSANZ considers that such regulatory measures would be excessive given that there have been no reported tutin poisonings associated with honey that meets the existing MLs since their introduction in the Code and since the introduction of the compliance options in the New Zealand tutin standard (see section 1.3.2). Recent research indicates however that the current MLs may not adequately protect consumers and may result in adverse effects as observed in the human study. Reducing the tutin MLs in the Code would protect consumers from these adverse effects (see section 2.1). In order to determine the achievability of lower levels in honey the results of analyses conducted for compliance testing as specified in the New Zealand standard has been taken account of. Most honey produced in New Zealand over recent years would meet the proposed lower MLs.

### **2.2.1 Maximum level for tutin in honey**

In determining the appropriate ML for tutin in honey, a critical factor has been the finding that honey contains higher levels of tutin than previously recognised. This has arisen from the identification of tutin glycosides, a masked form of tutin, which are converted to free tutin when consumed. An additional finding is the observation of adverse health effects from the consumption of honey at the current ML of 2 mg/kg.

The current ML is therefore not considered to be appropriate as it is not protective of human health. Several other factors were also considered in determining an appropriate ML. As noted in SD1, there may be more sensitive individuals in the population who could experience more severe effects (e.g. nausea, vomiting and dizziness). Furthermore, there is variation in the ratio of tutin glycosides to tutin (free form) in different honey samples and thus a higher level of total tutin equivalents may be present in some honeys than that used in the human study, where some adverse effects were observed (see SD1).

Consequently, in order to protect consumers from adverse effects as reported in the human study, it is necessary to reduce the ML for tutin in honey to take account of these factors. A reduction in the ML by a factor of three is proposed. Based on this assessment, it is proposed that the ML for tutin in honey in the Code should be reduced from 2 mg/kg to 0.7 mg/kg.

As no method is currently available to quantify the tutin glycosides in honey, the continued use of a ML based on the level of tutin instead of total tutin equivalents (tutin + tutin glycosides) is necessary.

### **2.2.2 Maximum level for tutin in comb honey**

Because tutin distribution can vary widely across honey comb, comb honey has to be considered separately to honey (extracted/blended honey). The presence of high levels of tutin in certain honey may be diluted with other honey through the mixing process during production. This would provide a lower overall tutin level. For comb honey, however, the tutin level in a specific portion of comb could differ markedly from the tutin level in another part of the comb.

It is not feasible to test each individual portion of comb honey for tutin. A representative 'hive drip' sample of the comb honey is therefore tested. As this sample is a collection of the honey from the comb drip and leftover comb, there could be an overall dilution effect, whereby portions of comb that contain higher levels of tutin are diluted by portions which contain lower levels of tutin. As such, the tutin level determined for the representative sample could also differ markedly from the tutin level in a specific portion of comb.

As concluded in FSANZ's risk assessment, there are insufficient data on the potential variability of tutin distribution to characterise the risk for comb honey. In order to minimise the health risk posed by tutin in comb honey, lowering the ML to the current analytical limit of detection, 0.01 mg/kg<sup>4</sup>, is proposed.

### **2.2.3 Industry education**

FSANZ acknowledges that there may continue to be a varying degree of residual risk of tutin poisonings with any of the options considered in assessing this Proposal. This is due to a potential lack of awareness of tutin contamination and the requirements in the Code and the New Zealand tutin standard by some smaller beekeepers and hobbyists. Additional risk management strategies are in place to mitigate this risk, including ongoing compliance testing and enforcement by MPI and educational information for industry. MPI provides information for honey producers on tutin contamination and the relevant legislation on their website (MPI, 2014).

FSANZ is also aware that information on tutin contamination is sent to beekeepers byASUREQuality on registration of their hives (registration is a legal requirement in New Zealand). We are also aware that industry-driven out-reach communication material on tutin contamination has been developed by the New Zealand Bee Products Standards Council<sup>5</sup>. This includes a leaflet and DVD which is provided to every registered beekeeper. The DVD is also available to purchase in beekeeping supply shops.

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<sup>4</sup> Improvements to testing sensitivity since the introduction of the temporary maximum levels provide a current limit of detection of 0.01 mg/kg.

<sup>5</sup> Members of the Bee Products Standards Council comprises representatives from the National Beekeepers Association of New Zealand, Federated Farmers Bee Industry Group, New Zealand Honey Packers and Exporters Association and MPI

#### **2.2.4 Tutu plant prohibition**

Standard 1.4.4 prohibits a part or derivative of a variety of plants, including tutu, from being intentionally offered for sale as food. This could potentially be interpreted as prohibiting the sale of honey that contains tutin by natural occurrence. Prohibiting the sale of such honey, providing the levels do not adversely affect safety, was not FSANZ's intention when developing this Standard. FSANZ is therefore proposing a consequential amendment to the Standard to make clear that the sale of honey or comb honey containing tutin by natural occurrence is not prohibited from being offered for sale, providing it complies with the tutin MLs in Standard 1.4.1.

### **2.3 Risk communication**

A communication strategy has been developed for this Proposal. All calls for submissions are notified via the FSANZ Notification Circular, media release and through FSANZ's social media tools and Food Standards News. Subscribers and interested parties are also notified via email about the availability of reports for public comment.

The process by which FSANZ considers standard matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on the draft variation to the Code. Comments are specifically requested from the honey industry on the questions raised in the consultation Regulation Impact Statement in **Supporting Document 2 (SD2)**.

All public comments received are reviewed and considered before approval of a variation to the Code by the FSANZ Board.

Individuals and organisations making submissions on this Proposal will be notified at each stage of assessment.

#### **2.3.1 Targeted consultation**

As the issue of tutin in honey appears to be unique to New Zealand, FSANZ has worked closely with MPI while assessing this Proposal.

Regular updates have been presented to the New Zealand Bee Products Standards Council on the progress of this Proposal. In November 2013 and February 2014, the Council was advised on the likely lowering of the tutin MLs in the Code.

An article on this Proposal and expected release of the call for submissions was also included in the April 2014 edition of the New Zealand Beekeepers Journal.

FSANZ spoke at the New Zealand apiculture industry conference with MPI in late June 2014 on the proposed reduction to the MLs and the release of the call for submissions.

#### **2.3.2 World Trade Organization (WTO)**

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

There are no relevant international standards for tutin. Amending the Code to prescribe permanent MLs for tutin in honey and comb honey is unlikely to have a significant effect on international trade as:

- The presence of tutin in honey seems to be unique to New Zealand. As there are no reports indicating the presence of tutin in honey from any other country, it is considered highly unlikely that there would be any imposts on honey imported from other countries.
- The interim standard for tutin has been in place since 2009 for the primary purpose of protecting human health and safety.
- The continuation of a regulatory standard for tutin in the Code, should reassure international markets that this measure supports a comprehensive risk management program to ensure the safety of honey produced in New Zealand.

Therefore, notification to the WTO under Australia's or New Zealand's obligations under the WTO Technical Barriers to Trade or Sanitary and Phytosanitary Measures Agreement has not been considered necessary.

## **2.4 FSANZ Act assessment requirements**

When assessing this Proposal and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 59 of the FSANZ Act:

### **2.4.1 Section 59**

#### **2.4.1.1 Cost benefit analysis**

In assessing this Proposal, FSANZ is required to have regard to whether the direct and indirect benefits that would arise from a food regulatory measure developed or varied as a result of the proposal outweigh the costs to the community, Government or industry that would arise from the development or variation of the food regulatory measure.

There were four options identified for this assessment:

- Option 1: *Status Quo* – abandon the Proposal and let the temporary MLs for tutin expire. If this option was preferred, MPI would also revoke the New Zealand tutin standard.
- Option 2: Abandon the Proposal and let the temporary MLs for tutin expire and encourage the honey industry to adopt a code of practice. If this option was preferred, MPI would also revoke the New Zealand tutin standard.
- Option 3: Prepare a draft variation to Standard 1.4.1 to make the current temporary MLs for tutin the permanent MLs (remove the current expiration date).
- Option 4: Prepare a draft variation to Standard 1.4.1 to reduce the current ML for tutin in honey to 0.7 mg/kg and tutin in comb honey to 0.01 mg/kg, based on new research, and make these MLs permanent.

Under options 3 and 4, a draft variation to Standard 1.4.4 would also be prepared as discussed in section 2.2.4 above. This proposed consequential amendment is for clarity purposes and is not considered to be relevant for the cost benefit analysis.

A consultation Regulation Impact Statement (consultation RIS) has been completed for this Proposal as provided in **SD2**.

As the issue of tutin contamination of honey appears to be unique to New Zealand, the consultation RIS was prepared by MPI with assistance from FSANZ. The New Zealand Treasury held primary responsibility for reviewing and approving the consultation RIS in liaison with the Office of Best Practice Regulation (OBPR) in Australia (OBPR RIS ID: 13847).

The consultation RIS assesses the costs and benefits of each of the four options identified above. A summary of the analysis is provided below.

Option 1 has an overall net cost. While beekeepers that produce honey only for the domestic market will face lower costs, more people are likely to be poisoned than is currently the case. In addition, the New Zealand government would face the costs of revoking the New Zealand tutin standard and may face increased enforcement costs initially under the *Food Act 1981* and then the *Food Act 2014* and the *Animal Products Act 1999*<sup>6</sup>. Option 2 has an overall net cost as any code of practice would be very costly for the relatively small honey industry to develop and would not be able to be enforced by government. It would not provide adequate protection for consumers due to the potential for poisonings to occur as a result of having no legislative force behind it. Option 3 does not adequately protect consumers against the adverse effects found in recent research. It has a possible net cost as overseas markets may react negatively to the recent research not being taken into account in setting the MLs.

#### *Preferred Option*

The preferred option (Option 4) is to reduce the maximum level for tutin in honey from 2 mg/kg to 0.7 mg/kg and the maximum level for tutin in comb honey from 0.1 mg/kg to 0.01 mg/kg. It is the option that gives the highest net benefit and which takes full account of the risk analysis using the best available scientific evidence which FSANZ is required to have regard to under the FSANZ Act. It also meets the FSANZ Act objective to protect public health and safety and has regard to the desirability of an efficient and internationally competitive food industry.

#### *Consultation on cost benefit analysis*

Public submissions are now invited on the draft variations to the Code. Comments are also specifically requested from the honey industry on the questions raised in the consultation RIS (SD2). These questions relate to the analysis of the options, current blending and testing costs, impacts of reducing the MLs and the proposed implementation approach (see section 3.1 on the implementation approach below). The questions are repeated in Attachment C to this report but submitters are recommended to refer to the consultation RIS, as the questions pertain to the full analysis which is presented there.

#### **2.4.1.2 Other more cost effective measures**

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the Proposal.

#### **2.4.1.3 Any relevant New Zealand standards**

This is addressed in section 1.3.2 on the New Zealand Food (Tutin in Honey) Standard 2010.

#### **2.4.1.4 Any other relevant matters**

See sections 2.4.2 and 2.4.3 below.

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<sup>6</sup> The *Food Act 1981*, the *Food Act 2014* and the *Animal Products Act 1999* are New Zealand Acts. When the new *Food Act 2014* comes fully into force, it will replace the *Food Act 1981*.

## **2.4.2 Subsection 18(1)**

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

### **2.4.2.1 Protection of public health and safety**

The setting of reduced MLs as a permanent measure in the Code protects consumers from the risks arising from contamination of honey and comb honey by tutin.

### **2.4.2.2 The provision of adequate information relating to food to enable consumers to make informed choices**

No relevant issues concerning the provision of adequate information relating to food to enable consumers to make informed choices were identified for this Proposal.

### **2.4.2.3 The prevention of misleading or deceptive conduct**

No relevant issues relating to the prevention of misleading or deceptive conduct were identified for this Proposal.

## **2.4.3 Subsection 18(2) considerations**

FSANZ has also had regard to:

- **the need for standards to be based on risk analysis using the best available scientific evidence**

The interim MLs for tutin in honey and comb honey were established using the best available scientific evidence at the time. Since their introduction, additional scientific research has been completed to more accurately characterise the public health and safety risk arising from tutin contamination of honey.

The proposed permanent MLs are based on the most recent best available scientific evidence, in particular see section 2.1 above.

- **the promotion of consistency between domestic and international food standards**

There are no international food standards for tutin. The issue of tutin contamination of honey appears to be unique to New Zealand.

- **the desirability of an efficient and internationally competitive food industry**

The continued control of tutin in honey and comb honey should reassure international markets that all honey products produced in New Zealand are safe to consume. This regulatory measure supports an efficient and internationally competitive food industry.

- **the promotion of fair trading in food**

The proposed permanent MLs will apply to all honey and comb honey produced in New Zealand. As such, FSANZ does not foresee any issues relating to the promotion of fair trading in food.

- **any written policy guidelines formulated by the Ministerial Council<sup>7</sup>.**

There are no relevant policy guidelines for this Proposal.

### **3 Draft variation**

The draft variation is at Attachment A. The draft variation is intended to take effect on gazettal.

A draft explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislative Instruments.

#### **3.1 Transitional arrangements**

There are to be no transitional arrangements.

However, to minimise the impact of the variations on the honey industry, FSANZ has developed a specific stock-in-trade provision for honey products. As honey can have a shelf life of around 5 years, the cost would be prohibitive to require re-blending of stock already packaged for retail sale that may not meet the new reduced MLs. Given that current laboratory test results indicate that a high proportion of honey samples already meet the proposed reduced MLs, the risk of adverse effects from existing stocks of retail honey products is expected to be low. FSANZ therefore proposes that any honey and comb honey that is packaged for retail sale before the date of gazettal is not required to comply at any time with the new reduced tutin MLs. These products will be required to comply with the ML requirements that applied in the Code before the variation commenced.

Honey that is not packaged for retail sale at the time of gazettal may require re-blending if it meets the existing ML for tutin in honey but not the new reduced ML. The honey industry will have prior notice of the potential lowering of the ML and on the release of this report (see section 2.3.1). This is expected to minimise the impacts of the proposed variation. Comb honey is currently required to meet a level of 0.01 mg/kg under the testing compliance option in the New Zealand tutin standard. The impact of the variation to the Code on comb honey not packaged for retail sale at the time of gazettal is therefore expected to be minimal.

Comments are specifically sought on the proposed implementation approach in the questions raised in the consultation RIS (section 7.1, SD2).

##### **3.1.1 Transitional arrangements for Code Revision**

FSANZ is reviewing the Code in order to improve its clarity and legal efficacy. This review is being undertaken through Proposal P1025 – details of which are on the FSANZ website<sup>8</sup>. FSANZ released a draft revision of the Code for public comment in May 2013. The draft revision has changed the Code's structure and format. A further draft revision of the Code and call for submissions will be released in July 2014.

The FSANZ Board is expected to consider P1025 and the proposed changes to the Code in late 2014. If approved, it is expected that the new Code will commence in 2015 and will repeal and replace the current Code. The new Code will then need to be amended to incorporate any outstanding changes made to the current Code, including the variations at Attachment A.

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<sup>7</sup> Now known as the Legislative and Governance Forum on Food Regulation

<sup>8</sup> <http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1025coderev5755.aspx>

### 3.1.2 Review

A further review of the proposed new tutin MLs is not intended. FSANZ would however consider reviewing the Standard if future reported poisonings indicated that the limit was not protective enough, or if further scientific evidence became available.

## 4 References

Ministry for Primary Industries, MPI (2014). Managing tutin contamination in honey <http://www.foodsafety.govt.nz/industry/sectors/honey-bee/tutin/index.htm>. Accessed 29 May 2014.

Ministry of Agriculture and Forestry, MAF (2010) (now Ministry for Primary Industries). Food (Tutin in Honey) Standard 2010. <http://www.foodsafety.govt.nz/elibrary/industry/tutin-honey-standard-2010.pdf>. Accessed 29 May 2014.

New Zealand Food Safety Authority, NZFSA (2008) (now Ministry for Primary Industries). Food (Tutin in Honey) Standard 2008. [http://www.foodsafety.govt.nz/elibrary/industry/Food\\_Tutin-Sets\\_Maximum.pdf](http://www.foodsafety.govt.nz/elibrary/industry/Food_Tutin-Sets_Maximum.pdf). Accessed 29 May 2014.

## Attachments

- A. Draft variations to the *Australia New Zealand Food Standards Code*
- B. Draft Explanatory Statement
- C. Consultation questions

## Attachment A – Draft variations to the *Australia New Zealand Food Standards Code*



### Food Standards (Proposal P1029 – Maximum Level for Tutin in Honey) Variation

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The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on the date specified in clause 3 of this variation.

Dated [To be completed by Standards Management Officer]

Standards Management Officer  
Delegate of the Board of Food Standards Australia New Zealand

**Note:**

This variation will be published in the Commonwealth of Australia Gazette No. FSC **XX on XX Month 20XX**. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

**1 Name**

This instrument is the *Food Standards (Proposal P1029 – Maximum Level for Tutin in Honey) Variation*.

**2 Variation to Standards in the Australia New Zealand Food Standards Code**

The Schedule varies Standards in the *Australia New Zealand Food Standards Code*.

**3 Commencement**

The variation commences on the date of gazettal.

**SCHEDULE**

**[1] Standard 1.4.1** is varied by

[1.1] omitting subclause 5(5), and substituting

“(5) Subclause 1(2) of Standard 1.1.1 does not apply to honey and comb honey for the purposes of the Table to clause 5.

(6) Notwithstanding subclauses 5(2) and (3), honey or comb honey that was packaged for retail sale before the commencement of the *Food Standards (Proposal P1029 – Maximum Level for Tutin in Honey) Variation* is taken to comply with this clause if the product otherwise complied with the Code before that variation commenced.”

[1.2] omitting from the Table to clause 5

“

Tutin	Tutin in honey Tutin in comb honey	2 0.1
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”

and substituting

“

Tutin	Honey Comb honey	0.7 0.01
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”

**[2] Standard 1.4.4** is varied by inserting after clause 1

**“1A Exemption for Tutin in honey and comb honey**

Clause 1 does not apply to Tutin that is present in honey or in comb honey by natural occurrence.”

## **Attachment B – Draft Explanatory Statement**

### **1. Authority**

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 2 of Part 3 of the FSANZ Act specifies that the Authority may prepare a proposal for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering a proposal for the development or variation of food regulatory measures.

FSANZ prepared Proposal P1029 to develop permanent maximum levels for tutin in honey and comb honey. The Authority considered the Proposal in accordance with Division 2 of Part 3 and has prepared a draft Standard.

### **2. Purpose**

The Authority has prepared a draft variation to Standard 1.4.1 – Contaminants and Natural Toxicants to reduce the maximum levels for tutin in honey and comb honey based on recent scientific evidence and set these as permanent levels. The setting of reduced permanent levels will protect consumers from the risks arising from tutin contamination of honey and comb honey.

The stock-in-trade provision provided for honey and comb honey packaged for retail sale prior to gazettal is expected to assist in minimising the impacts of the draft variation on the honey industry.

A consequential amendment to Standard 1.4.4 – Prohibited and Restricted Plants and Fungi is required to clarify that honey and comb honey which contains tutin by natural occurrence is not prohibited from being sold. Honey and comb honey containing tutin by natural occurrence is permitted to be sold, providing it complies with the maximum levels for tutin prescribed in Standard 1.4.1.

### **3. Documents incorporated by reference**

The variations to food regulatory measures do not incorporate any documents by reference.

### **4. Consultation**

In accordance with the procedure in Division 2 of Part 3 of the FSANZ Act, the Authority's consideration of Proposal P1029 will include one round of public consultation following an assessment and the preparation of a draft Standard and associated reports.

A Regulation Impact Statement was required because the proposed variations to Standard 1.4.1 are likely to have an impact on business and individuals.

### **5. Statement of compatibility with human rights**

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

## **6. Variation**

### **6.1 Standard 1.4.1**

Item [1.1] omits the current subclause 5(5) in Standard 1.4.1 to remove the expiry date which applies to the maximum levels prescribed for tutin in honey and comb honey in the Table to clause 5. This ensures that the new maximum levels will be a permanent measure in the Code.

The current subclause 5(5) is replaced with new subclauses 5(5) and 5(6).

Proposed subclause 5(5) expressly provides that the stock-in-trade provision in subclause 1(2) of Standard 1.1.1 does not apply to honey and comb honey for the purposes of complying with the maximum levels of tutin in honey and comb honey set out in the Table to clause 5.

Proposed subclause 5(6) provides a specific stock-in-trade provision so that honey or comb honey packaged for retail sale before the commencement of this variation will not have to comply with the new maximum levels for tutin. These products would have to comply with the maximum levels for tutin set out in the Code before the variation commenced.

Item [1.2] replaces the maximum levels for tutin in honey and comb honey in the Table to clause 5 with new reduced maximum levels.

### **6.2 Standard 1.4.4**

Item [2] inserts clause 1A into Standard 1.4.4 to clarify that the prohibition in clause 1 of the Standard in relation to the intentional addition of tutin to honey or comb honey or intentional offer for sale of honey or comb honey containing tutin, would not apply to tutin that is present in honey or in comb honey by natural occurrence (providing it meets the prescribed MLs).

## Attachment C – Consultation Questions

**NOTE:** If you provide answers to these questions please include information on the region where your hives are located and on your business type, for example: beekeeper, honey packer, or honey exporter. Submitters are recommended to refer to the consultation RIS (SD2), as the questions pertain to the full analysis which is presented there.

1. Are there any other options that are significantly different from the options presented that should be considered? If so, please provide information to support them.
2. Do you agree with the analysis of the likely costs and benefits of Option 1?
3. Do you have any additional information that you would like considered in this analysis?
4. Do you agree with the analysis of the likely costs and benefits of Option 2?
5. Do you have any additional information that you would like considered in this analysis?
6. How many kilograms of honey does your business blend to manage high tutin levels each year? What does this cost your business each year?
7. Does your business harvest comb honey from high risk areas at high risk times of the year? If so, how many tests do you undertake per year and what are the costs each year?
8. Do you agree with the analysis of the likely costs and benefits of Option 3?
9. Do you have any additional information that you would like considered in this analysis?
10. Do you agree with the analysis of the likely costs and benefits of Option 4?
11. What do you think that the additional costs per business or beekeeper would be to move from the temporary maximum level to the lower maximum level?
12. Do you think that the additional costs of this option are justified?
13. Do you have any additional information that you would like considered in this analysis?
14. If the maximum level is lowered to the suggested lower level, what volume of your honey do you estimate would not meet the lower level? What would be the likely impact on your business of this?
15. How much honey not packaged for retail sale will you have left from the year to June 2014 harvest period by December 2014? What proportion is this of the total amount of honey you harvested in the year to June 2014?
16. Do you agree with having no transitional arrangements for the implementation of the proposed permanent maximum levels for honey and comb honey given the new maximum levels would not apply to products packaged for retail sale prior to the changes being gazetted?
17. If you do not agree with having no transitional arrangements, what alternative do you suggest and why?